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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,384	01/05/2004	David John Targell	NGP0039	2667

832 7590 04/28/2005

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FORT WAYNE, IN 46802

EXAMINER
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STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/751,384	TARGELL, DAVID JOHN	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/4/04, 5/27/04</u>                                                      | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been received in this application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (5,417,660).

Martin shows a syringe holder that includes all the limitations recited in claim 1. See Figures 1-6 and the respective portions of the specification. Referring to claim 1, Martin shows a syringe holder with an elongated hollow body (12), a needle (92) connected to the flange (30) at the distal portion of said hollow body (12), and a retractable sleeve (14) that is capable of moving in and out of hollow body (12). The retractable sleeve (14) has a first position where the entire needle (92) (which constitutes a major portion) is covered by the retractable sleeve (14) (See Figure 2), a second position where the major portion of the needle (92) is exposed (See Figure 3),

and a third position (which is the same as the first position) where the entire needle (92) is covered and the sleeve (14) is locked in place (See Figure 1).

The retractable sleeve (14) includes stop members (50) and (52) which are guided by their respective tracks (40) and (42) in the inner wall of the hollow body (12) when the retractable sleeve (14) is moving from position to position.

In regard to claim 2, the stop members (50) and (52) are both flexible members. In order to unlock the sleeve (14) from the initial locked position stop members (50) and (52) must be depressed through apertures (80) and (82) in the wall of the hollow body (12). Therefore, stop members (50) and (52) must have substantial flexibility.

In regard to claim 3, the flexible members (50) and (52) are integrally formed on the sleeve (14).

In regard to claim 4, the sleeve (14) includes two flexible members (50) and (52). See Figure 1-3. Two flexible members constitute a plurality of flexible members.

In regard to claim 5, the sleeve (14) includes a plurality of flexible members (50) and (52) and each flexible member has its own respective track (40) and (42). Two tracks constitute a plurality of tracks.

In regard to claim 6, the upper portion of either flexible member (50) or (52) is the only part of the member that engages with the track and locks the sleeve (14) in place. The upper portion of the flexible member is defined as the part of the member that enters either aperture (80) or (82) in the hollow body (12). The upper portion constitutes a projection on the flexible member.

In regard to claim 7, the track (40) or (42) includes a first portion that permits the sleeve (14) to move from the first position to the second position. This portion extends from the proximal end (20) of the hollow body (12) to the distal end (22) of the hollow body (12). The track (40) or (42) also includes a second portion that permits the sleeve (14) to move from the second position to the third position. This portion extends from the distal end (22) of the hollow body (12) to the proximal end (20) of the hollow body (12).

In regard to claim 8, the hollow body (12) includes a stop, which is the inner wall of the apertures (80) and (82). The flexible members (50) and (52) engage the stop when the members enter through the apertures. This locks the sleeve (14) in the third position.

In regard to claim 9, the flexible members (50) and (52) can move into and out of the apertures (80) and (82) to unlock and lock the sleeve (14) in place. This constitutes a radial movement relative to the central axis of the hollow body (12).

In regard to claim 10, the sleeve (14) is held in its first position by the bias of a spring (16) which forces the flexible members (50) and (52) against the inner wall of the apertures (80) and (82) and prevents the sleeve (14) from moving.

In regard to claim 11, the sleeve (14) is prevented from slipping out of the hollow body (12) by contact with the stops (44) on the inner surface of the proximal end (22) of the hollow body (12). The portion of the hollow body (12) from the stops (44) to the end of the proximal end (20) can be considered an integrally formed collar on the hollow

body (12). This portion of the hollow body (12) makes contact with the sleeve (14) and prevents it from slipping out of the hollow body (12).

Claims 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin.

Martin shows a syringe holder that includes all the limitations recited in claim 12. See Figures 1-6 and the respective portions of the specification. Referring to claim 12, Martin shows a syringe holder with an elongated hollow body (12), a needle (92) connected to the flange (30) at the distal portion of said hollow body (12), and a retractable sleeve (14) that is capable of moving in and out of hollow body (12). The retractable sleeve (14) has a first position where the entire needle (92) (which constitutes a major portion) is covered by the retractable sleeve (14) (See Figure 2), a second position where the major portion of the needle (92) is exposed (See Figure 3), and a third position (which is the same as the first position) where the entire needle (92) is covered and the sleeve (14) is locked in place (See Figure 1).

The retractable sleeve (14) includes flexible fingers (50) and (52) which are guided by their respective tracks (40) and (42) in the inner wall of the hollow body (12) when the retractable sleeve (14) is moving from position to position.

In regard to claim 13, the sleeve (14) includes two flexible fingers (50) and (52) and each finger has its own respective track in the hollow body. See Figures 1-3. Two flexible fingers constitute a plurality of flexible fingers and two tracks constitute a plurality of tracks.

In regard to claim 14, the upper portion of either flexible finger (50) or (52) is the only part of the finger that engages with the track and locks the sleeve (14) in place.

The upper portion of the flexible finger is defined as the part of the member that enters either aperture (80) or (82) in the hollow body (12). The upper portion constitutes a projection on the flexible finger.

In regard to claim 15, the track (40) or (42) includes a first portion that permits the sleeve (14) to move from the first position to the second position. This portion extends from the proximal end (20) of the hollow body (12) to the distal end (22) of the hollow body (12). The track (40) or (42) also includes a second portion that permits the sleeve (14) to move from the second position to the third position. This portion extends from the distal end (22) of the hollow body (12) to the proximal end (20) of the hollow body (12).

In regard to claim 16, the hollow body (12) includes a stop, which is the inner wall of the apertures (80) and (82). The flexible fingers (50) and (52) engage the stop when the projections on the fingers (50) and (52) enter through the apertures. This locks the sleeve (14) in the third position.

In regard to claim 17, the flexible fingers (50) and (52) can move into and out of the apertures (80) and (82) to unlock and lock the sleeve (14) in place. This constitutes a radial movement relative to the central axis of the hollow body (12).

In regard to claim 18, the sleeve (14) is held in its first position by the bias of a spring (16) which forces the flexible fingers (50) and (52) against the inner wall of the apertures (80) and (82) and prevents the sleeve (14) from moving.

In regard to claim 19, the sleeve (14) is prevented from slipping out of the hollow body (12) by contact with the stops (44) on the inner surface of the proximal end (22) of

the hollow body (12). The portion of the hollow body (12) from the stops (44) to the end of the proximal end (20) can be considered an integrally formed collar on the hollow body (12). This portion of the hollow body (12) makes contact with the sleeve (14) and prevents it from slipping out of the hollow body (12).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to needle guards with retractable sleeves.

U.S. Pat. No. 5,688,241 to Asbaghi

U.S. Pat. No. 5,201,708 to Martin

U.S. Pat. No. 5,300,040 to Martin

U.S. Pat. No. 4,911,693 to Paris

U.S. Pat. No. 4,664,654 to Strauss

U.S. Pat. No. 5,104,384 to Parry

U.S. Pat. No. 5,088,986 to Nusbaum

U.S. Pat. No. 5,267,972 to Anderson

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS



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